As amended, Applicants respectfully submit that independent claim 1 defines over the combination of Willis in view of Mikhail. Respectfully, the cited references do not disclose a valve assembly that has a valve member formed at least in part by a material having a durometer of less than about 12 Shore. Support for this amendment can be found on at least lines 20-22 of page 2 and lines 6-13 of page 9 of Applicants' application.

Mikhail teaches that the valve membrane 38 may be made of a material that has a durometer value of about 12 to about 95 Shore (see Mikhail at column 9, lines 24-28). Mikhail fails to disclose a valve member that is formed at least in part by a material that has a durometer of less than about 12 Shore. One skilled in the art would not be motivated by the teachings of Mikhail to design a valve member that is formed at least in part by a material having a durometer of less than about 12 Shore because Mikhail specifically teaches towards a valve membrane 38 having a durometer value in the range of from about 12 to about 95 Shore. It would not have been obvious to one skilled in the art to go outside of the range disclosed in Mikhail because Mikhail further discloses that more preferred durometer values are between about 26 to about 60 Shore, about 35 to about 45 Shore, and most preferably about 40 Shore (see Mikhail at column 9, lines 28-30). As such, Mikhail teaches towards durometer values that are within the range of from about 12 to about 95 Shore, and specifically teaches that preferred values are at the higher end of the range. Consequently, Mikhail teaches against durometer values that are outside of the range of about 12 to about 95 Shore, and especially against values less than the lowest range limit.

As such, Applicants respectfully submit that independent claim 1 defines over the combination of Mikhail and Willis and is in condition for allowance. Further, all claims that depend directly from independent claim 1 (claims 2, 4, and 5) are also in condition for allowance. Their rejections being made moot due to the allowance of independent claim 1.

Independent claim 6 has been amended to call for a valve member that is formed at least in part by a material having a durometer of less than about 12 Shore.

Applicants submit that independent claim 6 defines over the combination of Willis and Mikhail for essentially the same reasons as discussed above with respect to independent claim 1. As such, Applicants submit that independent claim 6 is in condition for allowance and that claim 7 and newly added claim 28, which depend from independent claim 6, are also in condition for allowance. The rejection to dependent claim 7 being made moot due to the allowance of independent claim 6.

Independent claims 23 and 26 call for at least one of the flexible opposing walls to have a first portion with a durometer of about 50 Shore and a second portion having a durometer of less than about 20 Shore, the second portion being disposed at the respective end of the wall and the first portion being disposed spaced from the respective end. There is no suggestion or motivation of any sort in Mikhail to modify the flexible walls of a valve to have varying durometer values as set forth in claims 23 and 26. The valve membrane 38 in Mikhail is of a single durometer value. Applicants respectfully submit that independent claims 23 and 26 are allowable over the combination of Mikhail and Willis for at least this reason. Additionally, all claims which

depend from claims 23 and 26 (claims 24, 25, and 27) are also allowable. Their rejections being made moot due to the allowance of independent claims 23 and 26.

With the present amendment, Applicants submit that all pending claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested.

The Examiner is encouraged to contact the undersigned at his convenience to resolve any remaining issues.

Respectfully submitted,

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Amended Claims for U.S. Serial No.09/741,730 KCX-322 (KC #15927)

1. (Amended) A valve assembly for use in a medical product having a fluid path, the valve assembly configured to selectively pass fluids in one direction along the fluid path and to prevent backflow in the opposite direction along the fluid path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

the valve member formed at l

east in part by a material having a durometer of less than about [20] 12 Shore.

3. (Amended) The valve assembly as in Claim 1, wherein the valve member material has a durometer of about 8 to [15] less than about 12 Shore.

6. (Amended) A medical product defining a fluid path, the medical product comprising a valve

assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

the valve member formed at least in part by a material having a durometer of less than about [20] 12 Shore.

8. - 22. (Cancel)

28. (New) The medical product as in claim 6, wherein the valve member has a durometer of about 8 to less than about 12 Shore.